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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,383	05/26/2000	Joseph M. Vinetz	026.00101	7685

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/09/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/579,383

Applicant(s)

VINETZ, JOSEPH M.

Examiner

Padmavathi v Baskar

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--Th MAILING DATE of this communication app ars on the cover she t with the correspond nce address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 26 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached note.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached note.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 1-12, 23, 24 and 46.

Claim(s) withdrawn from consideration: 13-22 and 25-45.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: see attached note

### ADVISORY ACTION

1. The after final amendment filed on 8/26/03 has not been entered into the record because the proposed amendment does not overcome the rejections under 35 U.S.C. 112, first paragraph and does not place the application in condition for allowance. Further, the proposed claim 4 would raise the new issues with regard to 35 U.S.C. 112, first paragraph, written description and enablement. Claims 1-12, 23, 24 and 46 are under examination as an elected invention. Claims 13-22 and 25-45 are withdrawn from consideration as claims are drawn to non-elected inventions.
2. Although the examiner addressed all the issues on rejections of record in the final office action Paper # 10, the examiner chose to reply to applicant's arguments once again.
3. The rejection of claims 1-2 and 24 under 35 U.S.C. 102(b) as being anticipated by Sim et al 1989(Molecular and Biochemical Parasitology: 34:127-134) is maintained as set forth in the previous office action.

Applicants arguments filed on 8/26/03 have been fully considered but they are not deemed to be persuasive.

Applicant asserts that Sim et al does not disclose an isolated nucleic acid molecule as defined by the present specification on page14, lines 26-30, " isolated" refers to nucleic acid which has been separated from an organism in a substantially purified form and refers to MPEP 2173.05(a)

The claims are given the broadest interpretation consistent with the specification MPEP 2173.05(a). The claims are accordingly rejected because Sim et al disclose that infected mosquitoes were crushed and the DNA from sporozoites was denatured and isolated on to the filters and thus meet the limitation "an isolated nucleic acid molecule" of the claimed invention. However, with regard to " substantially purified form", applicant is arguing the limitation, which is

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not present in the claim. However, Sim et al disclose that sporozoites were separated from mosquitoes and DNA from sporozoites was denatured and isolated on to the filters. Therefore, the preparation is in a substantially purified form. Radiolabelled P.falciparum probe was shown to be (figure 3, rows a and b) hybridized with the isolated DNA on the filter. Therefore, the prior art disclosed the claimed invention.

4. With regard to rejection of claims 1-3, 6-12, and 24 under 35 U.S.C. 102(a) as being anticipated by Vinetz et al 1999(PNAS: 96:14061-14066), applicant's attention is drawn to the claims and Examiner's reply in Paper NO 10, Paragraph # 5.

Applicants arguments filed on 8/26/03 have been fully considered but they are not deemed to be persuasive.

Applicant asserts that Vinetz et al reference was published 11/23/1999 and the Office action in paper # 7 indicated that priority is granted as of 5/28/1999. Therefore, the rejection is improper and should be withdrawn.

The Office action in paper 7 has clearly indicated that claims 4 and 5 with respect to the SEQ.ID.NO: 1 and 3 accorded priority as of 5/28/99. However, the Examiner has not rejected the claims 4 and 5 under 35 U.S.C. 102(a) as being anticipated by Vinetz et al. The rejected claims are 1-3, 6-12, and 24 which are not drawn to SEQ.ID.NO: 1 and 3.

5. With regard to the rejection of claims 23 and 46 under 35 U.S.C. 112, first paragraph scope of enablement, Applicant asserts that the specification on page 17, line 1 through page 20 line 3 teaches how to make and use an isolated nucleic acid molecule encoding Plasmodium falciparum chitinase, said nucleic acid molecule encoding a first amino acid sequence having at least 90% amino acid identity to SEQ.ID.NO: 3 because the methods such as mutagenesis and screening are known which does not require an undue experiments.

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Applicant also states that it was well within the ordinary skill in the art how to make the claimed sequences having 90% identity, and cites MPEP 2164.02, 2164.02 and 2164.06.

The examiner has followed MPEP while rejecting these claims.

MPEP 2164 & MPEP 2164.01(a) state that the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.

MPEP 2164.08 states, "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation'." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

As examiner pointed in the previous office action paper # 10 that while general techniques are known, the specification fails to teach how the claimed nucleic acid molecule encoding a protein has been modified having at least 90% amino acid identity to SEQ.ID.NO: 3 that functions as the full length protein in blocking malaria parasite transmission to mosquitoes having chitinase activity. Further, the examiner showed how the art teaches that proteins with replacement of single amino acid residues may lead to both structural and functional changes that would not retain the biological activity. Therefore, one skilled in the art would have reason to doubt the function of an isolated nucleic acid molecule encoding Plasmodium falciparum chitinase, said nucleic acid molecule encoding a first amino acid sequence having at least 90% amino acid identity to SEQ.ID.NO: 3 that is required to practice the invention. Further, the specification does not disclose what other DNA from different stages of parasite, P.falciparum that encodes what other chitinases as the limitation "at least " broadly reads on any chitinase.

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6. The Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886.

The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/7/03

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